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(54) Phosthesis consisting of a heterologous collagen tube for use in hollow organ sutures.

(57) A radiopaque protesis consisting of a heterologous collagen tube for use in hollow organ sutures having tubular form with frusto-conical ends (2) and

provided with an annular rim (3) in an intermediate position, completed by a collagen strip to wrap the suture in the manner of a band.

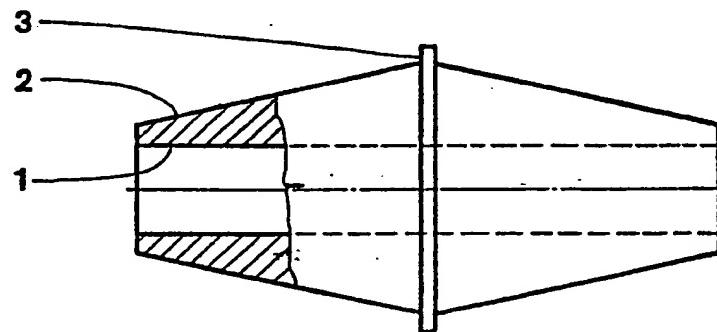


fig 1

**PROSTHESIS CONSISTING OF A HETEROLOGOUS COLLAGEN TUBE FOR USE IN HOLLOW ORGAN SUTURES**

This invention relates to a tubular prosthesis of heterologous collagen having considerable advantages when used in the formation of sutures on hollow organs.

In recomposing the two ends of a hollow organ after interruption of a segment, a suture is effected about the two ends after they have been placed properly face to face such that the mucous plane is perfectly positioned and each layer of one end perfectly coincides with the corresponding layer of the other end.

The prosthesis of the present invention is of particular use in ensuring success of this operation, in that it facilitates the manipulation of the suture and allows the ends to perfectly face each other.

Said prosthesis is particularly suitable for intestinal application, however if of suitable dimensions it can also be profitably used in sutures on the bile ducts and other hollow organs.

The prosthesis according to the present invention is characterised by being of tubular form with frusto-conical ends and provided with an annular rim in an intermediate position, and by being radiopaque.

The characteristics and advantages of said prosthesis will be more apparent from the following detailed description given with reference to Figure 1, which is provided by way of non-limiting example.

From said figure it can be seen that the prosthesis is of tubular form with a cylindrical inner surface 1 and an outer surface 2 with frusto-conical ends. The length of the prosthesis can vary from 15 to 150 mm and its inner diameter from 2 to 14 mm. The outer diameter can vary from 10 to 20 mm at the ends and from 20 to 50 mm in the intermediate position.

The prosthesis dimensions can be modified manually to satisfy requirements, including at the moment of application. For example its length can be reduced by cutting the ends with scissors, and its diameters and thickness can be varied by compression.

In the intermediate position the prosthesis comprises the annular rim 3 which has a thickness of between 1 and 2 mm and projects by between 2 and 3 mm.

The prosthesis material is made radiopaque either by inserting a radiopaque wire or by mixing with barium sulphate.

The frusto-conical ends of the prosthesis facilitate its insertion into the lumen of the ends of the organ concerned, whereas the annular rim 3 allows better anchorage of the prosthesis to the suture

and the integration of the suture with the collagen, in order to properly obliterate the suture and exert a coagulating effect on any small vessels which might bleed.

5 If desired, the described prosthesis can be completed by a collagen strip of thickness between 1 and 2 mm and width of between 20 and 30 mm, to wrap the suture in the manner of a band. The tubular prosthesis performs the important function 10 of protecting the operated area from contamination by feces while allowing gaseous, liquid and solid matter to pass, whereas the collagen strip performs the double function of protection against infection originating from the outside and providing a barrier 15 against any adhesion arising.

A further advantage of the prosthesis according to the present invention is that it promotes optimum cicatrization.

The collagen used to prepare the prosthesis is 20 of the lyophilized type and is reabsorbed by lysis in a time of not less than 3 days. The prosthesis can contain, adsorbed on its surface, substances of pharmacological action such as antibiotics, anti-inflammatories, hormones, bonding substances 25 such as fibrin and polyacrylates, cicatrization factors such as fibronectin, EGF, PGF etc. It can be integrated with systems for checking the cicatrization regularity, with tagged systems, with enzymatic systems or with cellular systems.

30 The prosthesis can also be previously inserted into other parts of the body such as under the skin or in the peritoneum, to be epithelialized, endothelialized or covered with a fibrinous or fibrous substance for particular uses.

35 The prosthesis can be applied either at ambient temperature or at a temperature of 4°C if it is considered desirable to make its adhesion more stable during the suture.

#### 40 Claims

1. A prosthesis consisting of a heterologous collagen tube for use in hollow organ sutures, characterised by being of tubular form with frusto-conical ends and provided with an annular rim in an intermediate position, and by being radiopaque.
2. A prosthesis as claimed in claim 1, characterised in that said tube has a cylindrical inner surface (1) and an outer surface (2) with frusto-conical ends.
3. A prosthesis as claimed in claim 1, characterised by having a length of between 15 and 150 mm and an inner diameter of between 2 and 14 mm.
4. A prosthesis as claimed in claim 1, characterised

by having an outer diameter of between 10 and 20 mm at its ends and between 20 and 50 mm in its intermediate position.

5. A prosthesis as claimed in claim 1, characterised in that said annular rim (3) has a thickness of between 1 and 2 mm and projects by between 2 to 3 mm.

6. A prosthesis as claimed in claim 1, characterised in that said radiopacity is obtained by inserting a radiopaque wire into the collagen.

7. A prosthesis as claimed in claim 1, characterised in that said radiopacity is obtained by mixing barium sulphate into the collagen.

8. A prosthesis as claimed in claim 1, characterised by being completed by a strip of collagen to be wrapped around the suture in the manner of a band.

9. A prosthesis as claimed in claim 8, characterised in that said collagen strip has a thickness of between 1 and 2 mm and a width of between 20 and 30 mm.

10. A prosthesis as claimed in claim 1, characterised in that said collagen is of lyophilized type, reabsorbable by lysis in a time of not less than three days.

11. A prosthesis as claimed in claim 1, characterised by containing, adsorbed on its surface, substances such as antibiotics, anti-inflammatories, hormones, bonding substances and cicatrization factors.

12. A prosthesis as claimed in claim 1, characterised by being integrated with systems for checking the cicatrization regularity, with tagged systems, with enzymatic systems or with cellular systems.

13. A prosthesis as claimed in claim 1, characterised by being previously inserted into other parts of the body, to be epithelized, endothelialized or covered with a fibrinous or fibrous substance.

14. A prosthesis consisting of a heterologous collagen tube for use in hollow organ sutures, as claimed in claims 1 to 13 and as described and illustrated for the specified objects.

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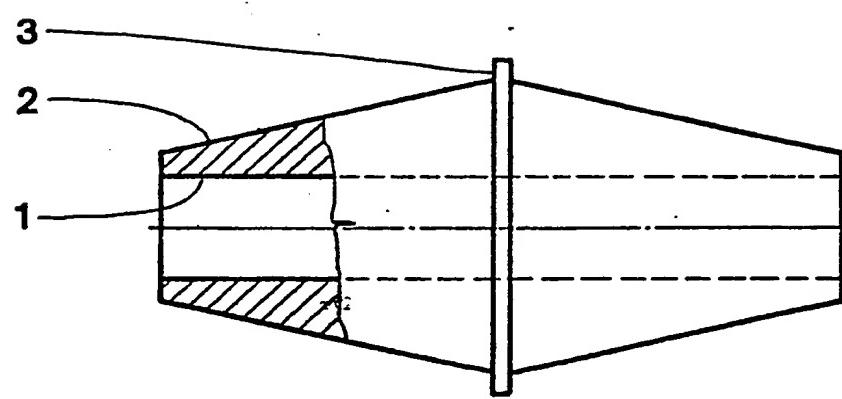


fig 1



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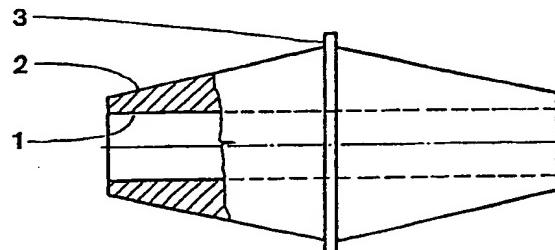


fig 1



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REPORT

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EP 90 11 2093

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	DE-A-2 547 265 (SCHÖNBACH) * Page 5, lines 8-22; figure 1 *	1-14	A 61 L 27/00 A 61 B 17/11
Y	GB-A-4 893 16 (DAVIS & GECK) * Page 1, lines 33-58; page 2, lines 44-52; figure 2 *	1-14	
A	US-A-4 719 916 (RAVO) * Abstract; figure 6 *	6,7	
A	US-A-3 726 279 (BAREFOOT et al.) * Abstract; figure 2 *	8,9	
A	EP-A-0 298 533 (SURGICAL RESEARCH) * Claims 1,5,9,12-15 *	1,8,9,11, 12	
A	EP-A-0 284 789 (ISTITUTO GENTILI) * Column 1, lines 25-31; claim 1 *	10	
A	US-A-3 938 524 (SPARKS) * Column 2, line 51 - column 3, line 9 *	13	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 B A 61 L A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	21 May 91	MOERS R.J.
CATEGORY OF CITED DOCUMENTS		
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